PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barella et al.	)	Examiner: Winston, R.
		)	
Serial No.:	10/537,452	)	Group Art Unit: 1655
		)	
		)	Confirmation Number 3265
		)	
Filed:	June 3, 2005	)	Attorney Docket: DSM-01-US
		)	
Title:	NOVEL USE OF LYCOPENE	)	

REQUEST FOR CONTINUED EXAMINATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Request for Continued Examination is submitted in response to the Final Office Action dated July 22, 2009. A Response to Final Office Action was previously filed on October 22, 2009, but no response was provided to the Applicant.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

Remarks begin on page 3 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. – 37. (Cancelled).

38. (Currently amended) A method of incidence risk reduction of polycystic ovary ~~symptom~~ syndrome associated with androgen signaling, comprising administering to a human at risk for polycystic ovary ~~symptom~~ syndrome an effective amount of lycopene to reduce androgen signaling.

39. (Previously presented) A method as in claim 38 wherein about 0.25 mg to about 50mg of lycopene are administered per day.

40. (Previously presented) A method as in claim 39 wherein about 1 mg to about 30 mg of lycopene are administered per day.

41. (Previously presented) A method as in claim 39 wherein, additionally, about 15 to about 600 mg of vitamin E are administered per day.

42. (Previously presented) A method as in claim 39 wherein, additionally, about 50 to about 1000 mg of vitamin C are administered per day.

43. (Previously presented) The method according to claim 38 wherein, additionally, an amount of lycopene is administered which results in a plasma concentration of 0.01 to 6 μM

REMARKS

I. Introduction

Following entry of the present amendment, claim 38 has been amended. Support for the amendment to claim 38 may be found in the specification as originally filed, e.g., page 7, lines 15 - 18. It is believed no new matter has been added.

II. 35 USC § 103(a) rejection

Claims 25 – 37 are rejected under 35 USC 103(a) as being unpatentable over Lorant et al. (US 6,623,769) in view of Murad (US 5,962,517) and de Salvert (US 5,827,520)Lorant in view of de Salvert (US 5,827,520), and further as evidence by Polycystic Ovarian Syndrome (website of www.medicinenet.com/polycystic_ovary/article.htm).

The Examiner finds Lorant et al. teaches an effective amount of lycopene is administered to treat acne (as evidenced by the Polycystic Ovarian Syndrome article) associated with androgen signaling, and would also inherently have the same underlining functional effect as the claimed invention, but does not teach the combination of lycopene and vitamins E and C administered to a subject in need thereof to treat pathologies associated with androgen signaling. However, the Examiner finds Murad teaches vitamin E treats pathologies associated with androgen signaling, and de Salvert teaches vitamin C treats pathologies associated with androgen signaling. Thus, according to the Examiner, it would have been obvious to one of skill in the art to modify the teachings of Lorant to include vitamin E and C as taught by Murad and de Salvert to practice the claimed invention. Applicants respectfully traverse the rejection.

Applicants thank the Examiner for discussing with them the reliance of Polycystic Ovarian Syndrome article in the present rejection. Applicants understand the article is cited as "evidence" that a symptom of polycystic ovarian syndrome is acne. However, Applicants strongly object to citation of the article, as no publication date is provided. Indeed, a search of the history of the website on archive.org reveals the website was published no earlier than April 5, 2004, which is after the priority date currently claimed by Applicants. Accordingly, the article cannot be considered prior art, and cannot be used as the basis for any rejection in the present application. In proving obviousness, the law requires that the asserted reference must be prior art to the claim. Even if the Examiner is using the article as "evidence," the article does not disclose acne was known to be a symptom of polycystic ovarian syndrome at the time the present

application was filed. Additionally, the MPEP does not allow or discuss the use of later filed references to be used as "evidence".

Lorant et al. utilizes lycopene in a mixture to have anti-collagenase activity. Lycopene is also taught to be useful in treatment of scalp/acne and use as an agent for combating free radicals. However, Lorant et al. is silent as to the activity of lycopene for the risk reduction of polycystic ovary syndrome. As previously provided, reliance on the Polycystic Ovarian Syndrome article as "evidence" of acne being a symptom of polycystic ovarian syndrome is improper. The Examiner finds Applicants admit that acne is also a disorder associated with androgen signaling at page 7 lines 27 - 29, but is using Applicant's own disclosure against themselves, which is impermissible.

Murad also deals with acne, and discloses a vitamin E source in combination with a host of other ingredients. Similar to Lorant et al., Murad is also silent on the use of vitamin E in risk reduction of polycystic ovary syndrome. The broad disclosures of Murad provides absolutely no suggestion or guidance to specifically select vitamin E and incorporate it into compositions for use in the presently claimed methods.

de Salvert fails to remedy the deficiencies of Lorant et al and Murad. Salvert is a topical composition containing, for example, vitamin C, in a particular vehicle which is transparent or translucent, homogenous and stable (in the absence of a surfactant and/or stabilizer). Similar to Murad, Salvert fails to teach or suggest risk reduction of polycystic ovary symptom associated with androgen signaling, and its broad disclosure does not teach or suggest any composition or benefit of adding vitamin C to a compositions comprising lycopene to reduce the risk of polycystic ovary syndrome.

The Examiner argues "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose...." [1] However, the provisions of MPEP § 2144.06 are inapposite to the present claims. This is not a case of combining equivalents known for the same purpose, or substituting equivalents known for the same purpose. None of the references teach or suggest lycopene, vitamin E and vitamin C are equivalents, or may be substituted for one another to achieve a common effect.

---

[1] Although the Examiner cited § 2114.06, Applicants believe the Examiner intended to cite § 2144.06, and request clarification if they are in error.

Mere identification in the prior art of each component of a composition does not show that the combination as a whole lacks the necessary attributes for patentability, i.e., is obvious. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). To establish a prima facie case of obviousness based on a combination of elements in the prior art, the law requires a motivation to select the references and to combine them in the particular claimed manner to reach the claimed invention. *Eli Lily and Co. v. Zenith Goldine Pharma., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006). In the present case, none of the references teach of suggest incidence risk reduction of polycystic ovary syndrome by the administration of lycopene. The disclosures of Murad and de Salvert do not teach or suggest any benefit of combining vitamins E or C into compositions containing lycopene for risk reduction of polycystic ovary syndrome, and Applicants submit the Examiner's reliance on Polycystic Ovarian Syndrome article is in error. As the rejection under 35 USC 103(a) is improper, Applicants request it be withdrawn.

V. Summary

Applicants have made a *bona fide* attempt to address all matters raised by the Examiner. Applicants respectfully submit that the application is now in condition for allowance, and therefore respectfully request that the outstanding rejections be withdrawn and that a Notice of Allowance be issued. If any remaining matters need to be resolved, Applicants respectfully request an interview with the Examiner prior to any official action being taken by the Office in response to these arguments and amendments in order to facilitate allowance of the pending claims.

It is believed fees, other than the filing fee and extension of time fee, are presently required. If a fee is required, please charge the same to Deposit Account 50-4255.

Respectfully submitted,

Date: 22 Jan 2010

By _____

Arthur Yang
Reg. No. 45,721
HOXIE & ASSOCIATES LLC
75 Main Street Suite 301
Millburn, NJ 07041
(973) 912-5232